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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,537

08/29/2006

Richard Gallo

00015-019US1/SD2004-043-2

1656

26138 7590 04/03/2009
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EXAMINER

GUPTA, ANISH

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

04/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,537	GALLO ET AL.	
	Examiner	Art Unit	
	ANISH GUPTA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) 9-39 and 45-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 40-44 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5-3-06, 8-17-07</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-9, 40-44, drawn to purified polypeptides, classified in class 514, subclass 2.
 - II. Claims 10-18, drawn to isolated polynucleotide sequences and vectors, classified in class 435, subclass 69.1.
 - III. Claims 19-39, 50-68, drawn to method of inhibiting growth of microbes, classified in class 514, subclass 2.
 - IV. Claims 45-49, drawn to method of stimulating LL-37 activity using a carbonate compound, classified in class 424, subclass 686.

The inventions are distinct, each from the other because of the following reasons:

The products of Group I and Group II are independent and distinct as a result of their structures. Polynucleotide and polypeptides are structurally distinct and do not anticipate nor render obvious one another. Furthermore, a search for each is based on its structure and would require independent structure searches in the art.

Inventions Group I and Group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case other cathelicidins, such as FALL39, can be used to practice the invention of Group III.

Group III and IV are distinct from one another because of each method group utilizes different method steps. The method of Group IV requires the presence of a carbonate compound.

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This compound is not required in the practice of Group III. Furthermore, the end points of the methods are separate from one another since the method of Group IV does not involve the use of microbes.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include

(i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election

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without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct species

SEQ ID NO 13-28 in Groups I and III. And a polynucleotide that encodes SEQ ID NO 13-28 for Group II.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1-39, 50-68 are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or

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the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

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During a telephone conversation with Joseph Baker on March 11, 2009 a provisional election was made without traverse to prosecute the invention of Group I, claim 1-9 and 40-44. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-39 and 45-68 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicants also elected species of SEQ ID NO: 13. A search was conducted for the elected species and prior art was found that anticipated the species. In course for searching for the elected species, other species were found, corresponding to SEQ ID 13-27. These species have been applied in the rejection below. This species reads on claims 1-8 and 40-44. Claim 9 is withdrawn from consideration as corresponding non elected species.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-8 and 40-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 and 2 recite that the length of the amino acid sequence is between 16-36 amino acids. However, the claims, when reciting the specific sequences recite NH₂-KRIVQRIKDFLRNLVP-COOH. This is also recited in based claim 1. Note that the terminal ends of the sequence are closed with NH₂ and COOH. It is unclear how the sequence can be of a larger length when the terminal ends seem to be closed to the addition of other amino acids.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3, 5, 7, 8 and 40-42 rejected under 35 U.S.C. 102(e) as being anticipated by Stahle-Backdahl et al. (US7452864).

The claims are drawn to antimicrobial peptides.

The reference discloses peptides fragments from the LL-37 sequence. The reference specifically disclose peptides of the sequence

LLGDFFRKSKEKIGKEFKRIVQRIKDFLRNLVPRTE (see col. 5, lines 35-60). The reference also disclose the peptide LLGDFFRKSKEKIGKEFKRIVQRIKDFLRNLVPRT,

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LLGDFFRKSKEKIGKEFKRIVQRIKDFLRNLPVPR,

LLGDFFRKSKEKIGKEFKRIVQRIKDFLRNLVP which have a length of 35, 34, 33 amino acids in length (see same col.). The peptides disclosed contain the sequence of SEQ ID NO 13-16, contains SEQ ID NO: 18-21 and SEQ ID NO 23-26. Since the peptides taught are of 33-36 amino acids in length, the prior art meets the limitation of claims 1 and 8. The reference disclose pharmaceutical formulations for the peptides for topical, oral, buccal, mucosal and nasal administration (see col. 8, lines 64-67). The reference disclosed formulations comprising gel, thereby meeting the limitation of claim 41 (see col. 8, lines 36-54).

The reference anticipates the claimed invention.

4. Claims 1, 3-7, 40 and 42-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Johansson et al. (J. of Biol. Chem.).

The claims are drawn to antimicrobial peptides.

The reference discloses the peptide of the sequence FFRKSKEKIGKEFKRIVQRIKDFLRNLPVPRTES and SKEKIGKEFKRIVQRIKDFLRNLPVPRTES (see page 3719). Note that these two peptides have a length of 33 and 29 amino acids respectively, which meet the limitation of claims 4 and 6. The peptides contain the sequences corresponding to SEQ ID 17, SEQ ID 22 and SEQ ID 27 of the claimed invention. The reference discloses formulations comprising NaHCO₃ to test against antimicrobial activity (see page 3719). Thus, the reference meets the limitation of the claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-8 and 40-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 and 26 of copending Application No. 10/575552. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The claims are drawn to antimicrobial peptides.

The provisional application claims peptides for the treatment of viral infections. The peptides claimed correspond to the sequence KRIVQRIKDFLRNLVP, KRIVQRIKDFLRNLVPR, KRIVQRIKDFLRNLVPRT, KRIVQRIKDFLRNLVPRTE, KRIVQRIKDFLRNLVPRTES, KSEKIGKEFKRIVQRIKDFLRNLVP, KSEKIGKEF KRIVQRIKDFLRNLVPR, KSEKIGKEF KRIVQRIKDFLRNLVPRT, KSEKIGKEF KRIVQRIKDFLRNLVPRTE, KSEKIGKEF KRIVQRIKDFLRNLVPRTES (see claim 4 and 6). These sequences correspond to the instant claims 3 and 5. Note that the application also claims similar length and claims that the method of treating can be practiced by topical formulations (see claim 26). In practicing the claimed invention

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of the US application, one would have to obtain the instantly claimed peptides in a pharmaceutical formulation. Thus, the claimed peptides are not patentably distinct from the US patent Application.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.

/Anish Gupta/
Primary Examiner, Art Unit 1654